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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,409

12/20/2005

Luciano Alcidi

71977

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SCARBOROUGH STATION

SCARBOROUGH, NY 10510-9227

EXAMINER

DICICCO, JOHN R

ART UNIT

PAPER NUMBER

3709

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/551,409

Applicant(s)

ALCIDI, LUCIANO

Examiner

John R. Di Cicco

Art Unit

3709

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 Decemeber 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☒ Claim(s) 1,2,4,5 and 9-13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 December 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>29 September 2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is responsive to the non-provisional application filed on December 20, 2005. Claims 1-13 are pending. Claim 1 is independent.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "13" has been used to designate both detector circuit and display. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to because Fig.1, reference number 13 does not clearly distinguish the detector circuit from the display . Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing

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should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to because on page 4 of the drawings, there are five drawings and only four labeled figures, i.e. Fig. 4A, 4B, 5A, and 5B. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top

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margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

5. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

6. The abstract of the disclosure is objected to because the legal phraseology "means" and "said" have been used, and the abstract is not within the range of 50 to 150 words. Correction is required. See MPEP § 608.01(b).

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in

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upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.**
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.**
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).**
- (i) DETAILED DESCRIPTION OF THE INVENTION.**
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

7. The disclosure is objected to because of the following informalities: (a) The above arrangement of the specification has been provided to assist the applicant with labeling and organizing the specification (see above bolded letters f-i). (b) The reference number "13" is used for two different features. (c) Brief description of drawings: On page 2 of the specification, there are more drawings than drawings described.

Appropriate correction is required.

Claim Objections

8. Claims 1 and 9-13 are objected to because of the following informalities: It is unclear if the word "it" is referring to apparatus, active electrode, or reference electrode. Appropriate correction is required.

9. Claim 2 is objected to because of the following informalities: It is unclear what "means comprise" is referring to. Appropriate correction is required.

10. Claims 4 and 5 are objected to because of the following informalities: With respect to claim 4, line 3 after "and" should not have a period, and with respect to claim 5, line 3 after "generating" should not have an apostrophe. Appropriate correction is required.

Claim Rejections - 35 USC § 112

11. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 11, the word "means" is preceded by the word(s) "application" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-3 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Wiksell et al. (4,846,196). Furthermore, 35 U.S.C. 112, sixth paragraph has been invoked due to “means plus function” language in claims 1 and 2.

With respect to claim 1, Wiksell et al. teaches the claimed apparatus for non-destructive hyperthermia therapies, characterized in that it comprises means for generating radio-frequency electromagnetic radiations, connectable to means for the application of said radiations to the human body (abstract).

With respect to claim 2, Wiksell et al. teaches an active electrode and a reference electrode (Fig.1, #2, #6), where the active electrode is being provided with means for the detection of the skin's temperature (column 9, lines 50-51).

With respect to claim 3, Wiksell et al. teaches the said means for the detection of the skin's temperature, which are made up of at least a sensor incorporated in the electrode (column 7, lines 26-28).

With respect to claim 6, Wiksell et al. teaches the said electrodes, which consist of conductive plates or membranes (column 6, lines 31-37).

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With respect to claim 7, Wiksell et al. teaches the structure of the active electrode is complementary shaped with respect to the body's region of the patient to be treated (column 6, lines 31-37).

With respect to claim 8, Wiksell et al. teaches the said reference electrode, which has dimensions larger than those of the active electrode (column 4, lines 8-17).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 4 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiksell et al. (4,846,196) in view of Cosman et al. (2002/0111617). Furthermore, 35 U.S.C. 112, sixth paragraph has been invoked due to "means plus function" language.

With respect to claim 4, Wiksell et al. discloses the invention set forth above but fails to teach the said means for the detection of the skin's temperature which are made up of at least a sensor which can be connected to the apparatus and removably associated with the active electrode in correspondence of a relevant seat thereof as in the instant claimed invention.

However, Cosman et al. teaches two electrode rings on a flexible catheter with removable insulative bands and temperature sensors (column 4, lines 27-32; Fig. 8).

It would have been obvious to one of ordinary skill in the hyperthermia art to have modified Wiksell et al. with removable temperature sensors as taught by Cosman et al. because it would have enabled the device to incorporate removal or attachment of temperature sensors.

With respect to claim 11, Wiksell et al. discloses the invention set forth above but fails to teach the apparatus characterized in that it comprises means for measuring the

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output power and the impedance in correspondence of the application means as in the instant claimed invention.

However, Cosman et al. teaches a generator which can have many control and readout functions associated with the RF parameters of the ablation process which include display output power, current, voltage, impedance, or other parameters associated with the heating process (columns 6-7; lines 65-2).

It would have been obvious to one of ordinary skill in the hyperthermia art to have modified Wiksell et al. with a generator which has many control and readout functions as taught by Cosman et al. because it would have enabled the device to display output power and impedance, thus enabling manual control of the parameters.

With respect to claim 12, Wiksell et al. discloses the invention set forth above but fails to teach the apparatus characterized in that it comprises means to preset the duration of the treatment as in the instant claimed invention.

However, Cosman et al. teaches control aspects of the generator that manually, automatically, or by computer control govern and monitor the process and parameter display of RF signal application to the electrodes and time parameters during the procedure (column 7, lines 3-7). Furthermore, Cosman et al. teaches the electrode which is used to heat tissue for three minutes and five minutes (column 6, lines 60-64).

It would have been obvious to one of ordinary skill in the hyperthermia art to have modified Wiksell et al. with a generator as taught by Cosman et al. because it would have enabled the device to control time parameters of the treatment.

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18. Claims 5, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiksell et al. (4,846,196) in view of Takayama et al. (5,003,991). Furthermore, 35 U.S.C. 112, sixth paragraph has been invoked due to "means plus function" language.

With respect to claim 5, Wiksell et al. discloses the invention set forth above but fails to teach the said means for the detection of the skin's temperature which are connected to a control circuit connectable to and acting on said means for generating radio-frequency radiations.

However, Takayama et al. teaches a controller which supplies a control signal to the variable impedance matching circuit such that the input impedance of the load circuit including two electrodes selected by the switch is matched to the output impedance of the RF power supply device including the co-axial cable (column 7, lines 51-56) and for instance, when the electrodes are switched into or out of the circuit by the switch, the RF power is decreased to zero, and when the sensed temperatures increase, the RF power is switched OFF or ON (column 7, lines 61-66).

It would have been obvious to one of ordinary skill in the hyperthermia art to have modified Wiksell et al. with a control circuit as taught by Takayama et al. because it would have enabled the device to switch the RF power on or off depending on the sensed temperature from the control circuit.

With respect to claim 9, Wiksell et al. discloses the invention set forth above but fails to teach the apparatus, which comprises more active electrodes connected to a switch device able to connect in sequence said active electrodes to said means for generating radio-frequency radiations.

However, Takayama et al. teaches a selection switch which serves to connect a first combination of the first and second electrodes and or a second combination of the second and third electrodes and to a high frequency power supply source so that an electric field of a Radio Frequency can be applied across the electrodes (column 5, lines 31-37; Fig. 3).

It would have been obvious to one of ordinary skill in the hyperthermia art to have modified Wiksell et al. with a switch as taught by Takayama et al. because it would have enabled the device to connect electrodes with a power supply source so that an electric field of a Radio Frequency can be applied across the electrodes (Fig. 3).

With respect to claim 10, Wiksell et al. discloses the invention set forth above but fails to teach the apparatus characterized in that it comprises means for adjusting the temperature reached on the skin and able to vary the output power in order to keep the skin's temperature at a preset value as in the instant claimed invention.

However, Takayama et al. teaches a hyperthermia apparatus for effecting the thermotherapy by heating a cancer locally including two outside-body electrodes, and a switch connected between the high frequency power supply circuit and the electrodes for selectively supplying the high frequency power to two electrodes so that the cancer can be locally heated to a desired high temperature (abstract).

It would have been obvious to one of ordinary skill in the hyperthermia art to have modified Wiksell et al. with a switch as taught by Takayama et al. because it would have enabled the device to selectively supply power to the outside-body electrodes at a desired temperature.

19. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wiksell et al. (4,846,196) in view of Turner (4,798,215). Furthermore, 35 U.S.C. 112, sixth paragraph has been invoked due to "means plus function" language.

Wiksell et al. discloses the invention set forth above but fails to teach the apparatus characterized in that it comprises means for connection with an electronic processor as in the instant claimed invention.

However, Turner teaches the hyperthermia and receiver subsystems which include, respectively, a power source and radiometer connected to a switch controlled by a central processing unit (abstract).

It would have been obvious to one of ordinary skill in the hyperthermia art to have modified Wiksell et al. with a processor as taught by Turner because it would have enabled the device a processor to be connected with, which inherently requires a means for connection.

Correspondence


Any inquiry concerning this communication or earlier communications from the examiner should be directed to John R. Di Cicco whose telephone number is (571) 270-5039. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Del Sole can be reached on (571) 272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JRD


JOSEPH DEL SOLE
SUPERVISORY PATENT EXAMINER
9/25/07